

**REMARKS**

Claims 1-23 were pending in the application. Claims 1, 3-6, 8-11, and 14 have been amended. Upon entry of these amendments, Claims 1-23 will be pending and under active consideration. Claims 1, 6, 11, 12, and 18 are independent.

Applicants submit respectfully that the amendments presented herein are supported fully by the claims and/or specification as originally filed and, thus, do not represent new subject matter.

Claim 1, 3-6, 8-11, and 14 have been amended to more particularly point out and more distinctly claim that which Applicants regard as their invention by employing closed language with regard to the components of the claimed compositions and to recite that the claimed smooth muscle relaxants are phytotherapeutic agents. No new matter was added.

Applicants respectfully request entry of the amendments and remarks made herein into the file history of the present invention. Reconsideration and withdrawal of the rejections set forth in the above-identified Office Action are respectfully requested.

**I. The Rejections Under 35 U.S.C. § 102(e) Should Be Withdrawn**

The Final Office Action, at pages 2-3, rejects Claims 1-3, 6-8, and 11-23 as allegedly being anticipated by U.S. Patent No. 6,231,866 to Mann (hereinafter, "Mann") or by Published U.S. Patent Application No. 2001/0008638 A1 to Wilding (hereinafter, "Wilding") under 35 U.S.C. § 102(e) for the reasons of record. In sum, the Final Office Action alleges that Mann teaches a saw palmetto extract in an

encapsulated controlled-release formulation as claimed by Applicants and that Wilding teaches a saw palmetto extract in an enteric-coated controlled-release formulation as claimed by Applicants. Applicants traverse respectfully.

Applicants submit respectfully that Claims 1-3, 6-8, and 11-23, as amended, are not anticipated by Mann because Mann does not disclose each and every element of the amended claims as is required for a *prima facie* showing of anticipation. In particular, Claims 1-3, 6-8, and 11-23, as amended, are directed to compositions consisting essentially of saw palmetto extract and a controlled release system. Applicants submit respectfully that, as acknowledged in the Final Office Action in the paragraph bridging pages 8-9, Mann teaches saw palmetto oil infused into a saw palmetto pomace. Accordingly, Applicants' present amendment, which amends the claims to employ closed language with respect to the ingredients of Applicants' claimed compositions, excludes compositions such as those taught by Mann.

Likewise, Applicants submit respectfully that Claims 1-3, 6-8, 11, and 18-23, as amended, are not anticipated by Wilding because Wilding does not disclose each and every element of the amended claim as is required for a *prima facie* showing of anticipation. As noted above, Claims 1-3, 6-8, 11, and 18-23, as amended, are directed to compositions consisting essentially of saw palmetto extract and a controlled release system. Applicants submit respectfully that, as acknowledged in the Final Office Action in the paragraph bridging pages 8-9, Wilding fails to teach a saw palmetto extract without pro-hormone. Accordingly, Applicants' present amendment, which amends the claims to employ closed language with respect to the ingredients of Applicants' claimed compositions, excludes compositions such as those taught by Wilding.

Accordingly, Applicants submit respectfully that Mann and Wilding do not anticipate Applicants' claims as amended, and Applicants request that the rejection of Claims 1-3, 6-8, and 11-23 under 35 U.S.C. § 102(e) be withdrawn.

## **II. The Rejections Under 35 U.S.C. § 103(a) Should Be Withdrawn**

The Final Office Action, at pages 4-8, rejects Claims 1-23 as allegedly being obvious over Wilding or Mann in view of U.S. Patent No. 6,200,573 to Locke (hereinafter, "Locke") and U.S. Patent No. 5,102,666 to Acharya (hereinafter, "Acharya") or, alternatively, over Published U.S. Patent Application No. 2002/0071868 A1 to Jia (hereinafter, "Jia") in further view of Wilding, Mann, Locke, and Acharya, under 35 U.S.C. § 103(a) for the reasons of record.

In sum, the Final Office Action alleges that Wilding and Mann teach the controlled-release formulation of Applicants' claims, but Wilding and Mann are deficient in that they do not teach the inclusion of a smooth muscle relaxant, in particular do not teach the particular agents recited in Applicants' Claims 5 and 10, and Mann is further deficient in not teaching the use of an enteric coating. The Final Office Action alleges that Locke cures the deficiency related to inclusion of a smooth muscle relaxant by teaching the use of a composition for treatment of BPH comprising saw palmetto extract and an alpha-adrenergic antagonist, that Acharya teaches the inclusion of peppermint oil as a flavoring (thus inherently providing Applicants' claimed relaxant activity to the preparations described above), and that Locke cures the deficiency related to lack of an enteric coating by teaching that the compositions can be formulated in sustained-release preparations by well-known techniques.

The Final Office Action further alleges that Jia teaches a bio-adhesive preparation including saw palmetto extract. While Jia does not teach the use of such an extract for treatment of BPH, the use of a controlled-release formulation, or the particular combinations claimed by Applicants, the Final Office Action alleges that Mann, Wilding, Locke, and Acharya cure the deficiencies of Jia by allegedly teaching a saw palmetto extract in a sustained-release formulation with smooth muscle relaxants, including peppermint (which was added as flavoring). Applicants traverse respectfully.

Applicants submit respectfully that the novel compositions and methods of the present invention are neither taught nor suggested by the cited references. As discussed above, Wilding and Mann neither teach nor suggest the use of a composition ***consisting essentially of*** saw palmetto extract and a controlled-release system for the treatment of symptoms of BPH. Wilding and Mann both teach that other components (*i.e.*, saw palmetto pomace and/or prohormones) must be added for effective use of the saw palmetto extract. Locke does not cure this deficiency because Locke also teaches that a further component should be included in the composition; namely, an alpha-adrenergic antagonist. Accordingly, Applicants submit respectfully that one skilled in the art would not find teaching within Wilding, Mann, or Locke to employ a composition ***consisting essentially of*** saw palmetto extract and a controlled-release system for the treatment of symptoms of BPH. Acharya and Jia do not discuss treatment of BPH or symptoms thereof at all and, therefore, cannot cure the deficiencies of Wilding, Mann, and Locke with regard to treatment of BPH.

With respect to Claims 4, 5, and 9-11, as amended, which recite compositions as above that further “consist essentially of a therapeutically effective amount of a

phytotherapeutic agent compound that minimizes smooth muscle contractions.” Applicants submit respectfully that the cited references do not teach or suggest the use of a therapeutically effective amount of such phytotherapeutic smooth muscle relaxing agents. As acknowledged in the Final Office Action, Mann and Wilding do not teach the use of smooth muscle relaxants, and Locke is alleged to cure this deficiency. However, Locke teaches solely the use of specific synthetic alpha-adrenergic antagonists; namely, terazosin, doxazosin, and tamsulosin (see Locke, Column 8, lines 4-16). None of these is a phytotherapeutic agent as recited in the claims, as amended.

Acharya is cited as providing a beneficial teaching of a plant-derived agent (peppermint) that is alleged to provide inherently the claimed smooth muscle relaxant property as part of a composition to treat BPH, thus curing the deficiency noted above in Wilding, Mann, and Locke. Although Acharya does teach the addition of peppermint oil **as a flavoring** to a controlled release pharmaceutical formulation, Applicants submit respectfully that Acharya neither teaches nor suggests that such use would be **therapeutically effective** or that the amount used as flavoring would be a **therapeutically effective amount** as claimed in the present claims, as amended. Accordingly, Acharya’s use of peppermint does not inherently provide the therapeutic effect claimed by Applicants, and one skilled in the art would not find teaching in Acharya to provide peppermint for its therapeutic effect of minimizing smooth muscle contractions. As Jia is cited merely as teaching a composition of saw palmetto extract with a bioadhesive, as is not alleged to teach treatment of symptoms of BPH or the inclusion of a phytotherapeutic agent in compositions for such treatment, Jia does not cure the deficiencies of Wilding, Mann, Locke, and Acharya in this respect. Thus,

Applicants submit respectfully that the combination of Mann and Wilding with Locke, Jia and/or Acharya fails to meet the threshold required for establishing a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

Accordingly, Applicants submit that the rejections of Claims 1-23 under 35 U.S.C. § 103(a) have been overcome, and Applicants respectfully request that the rejection of Claims 1-23 under 35 U.S.C. § 103(a) be withdrawn.

### **III. Rejections Under 35 U.S.C. § 112, Second Paragraph**

At pages 2 of the Office Action, Claim 11 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being vague and indefinite, for the reasons of record, for failing to point out particularly and claim distinctly the subject matter regarded as the invention. Applicants traverse respectfully.

Without acquiescing in the propriety of rejection, and solely to advance prosecution of the present application, Claim 11 is amended herein to remove the term "improved," added by previous amendment, and to add the clarification that the composition contains "a therapeutically effective amount of a saw palmetto extract." Accordingly, the claim is no longer a Jepson claim and is clear and unambiguous with regard to the presence of saw palmetto extract.

On this basis, Applicants suggest respectfully that the rejection has been overcome, and Applicants request respectfully that the 35 U.S.C. § 112, second paragraph, rejection of Claim 11 be withdrawn.

**CONCLUSION**

Applicants submit respectfully that the present application is in condition for allowance. Favorable reconsideration, withdrawal of the rejections set forth in the above-noted Office Action, and an early Notice of Allowance are requested.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

**AUTHORIZATION**

Applicants believe there is no fee due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,



Gilberto M. Villacorta, PH.D.  
Registration No. 34,038  
Robert R. Seabold, PH.D.  
Registration No. 41,298

Patent Administrator  
KATTEN MUCHIN ZAVIS ROSENMAN  
525 West Monroe Street, Suite 1600  
Chicago, Illinois 60661-3693  
Facsimile: (312) 902-1061

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